United States of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 112th CONGRESS, SECOND SESSION

Vol. 158 WASHINGTON, THURSDAY, MAY 17, 2012 *No. 71*

Senate

The Senate met at 9:30 a.m. and was called to order by the Honorable TOM UDALL, a Senator from the State of New Mexico.

PRAYER

The Chaplain, Dr. Barry C. Black, offered the following prayer:

Let us pray.

Eternal Savior, like a shepherd lead us, much we need Your tender care. Lead our Senators today away from cautious complacency and from impulses which can bring regrets. Lead them toward the freedom that trusts Your providence and believes that in everything You work for the good of those who love You.

Lord, give us all, by Your grace, pure hearts that love only the highest and clean minds that seek only the truth. Let nothing deflect us from Your path so we will always follow You and never lose our way.

We pray in Your sovereign Name. Amen.

PLEDGE OF ALLEGIANCE

The Honorable TOM UDALL led the Pledge of Allegiance, as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

The PRESIDING OFFICER. The clerk will please read a communication to the Senate from the President pro tempore (Mr. INOUYE).

The legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
Washington, DC, May 17, 2012.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable TOM UDALL, a Senator from the State of New Mexico, to perform the duties of the Chair.

DANIEL K. INOUYE,
President pro tempore.

Mr. UDALL of New Mexico thereupon assumed the chair as Acting President pro tempore.

RESERVATION OF LEADER TIME

The ACTING PRESIDENT pro tempore. Under the previous order, the leadership time is reserved.

RECOGNITION OF THE MAJORITY LEADER

The ACTING PRESIDENT pro tempore. The majority leader is recognized.

THE FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT—MOTION TO PROCEED

Mr. REID. Mr. President, I now move to proceed to Calendar No. 400.

The ACTING PRESIDENT pro tempore. The clerk will report the motion.

The legislative clerk read as follows:

Motion to proceed to Calendar No. 400, S. 3187, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Mr. REID. Mr. President, we are now on the motion to proceed to FDA user-fees legislation.

I ask unanimous consent that following my remarks and those of the Republican leader, the time until 10:30 a.m. be equally divided and controlled between the two leaders or their designees, with the Republicans controlling the first half and the majority controlling the final half.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. REID. Mr. President, at 10:30 a.m. today the Senate will proceed to executive session to consider the Stein and Powell nominations, both nominees to the Board of Governors at the Federal Reserve system. At noon, there will be two votes on the confirmation of their nominations. At this stage, there likely will be no more votes after that, but we will keep everyone advised as to what is going to happen.

Mr. President, when someone we love gets sick, the only thing on your mind is how to help them get well, how to get them the care they need.

But before every miracle drug or innovative new device comes to market, there is a rigorous approval process to make sure that device or that medicine is going to be safe. To get lifesaving drugs and devices to the patients who need them as quickly and efficiently as possible, Congress must give the Food and Drug Administration the tools it needs to review and approve these products. Today the Senate will begin consideration of legislation which gives FDA the resources to ensure medical devices, drugs, and treatments are safe and effective.

I applaud the work of my colleagues Senator HARKIN and Senator ENZI to bring this legislation to the floor. These two fine Senators have different political philosophies on things generally, but they work well on this committee and I am very proud of each of them. I consider them both friends. And bringing this bill to the floor in the manner they did is indicative of the work that needs to be done around here more often. So I hope to see the strong bipartisan effort these two Senators began continue as the Senate considers this important legislation.

The Food and Drug Administration Safety and Innovation Act authorizes the FDA to charge manufacturers of new medical devices user fees. These fees are used to ensure their products are reviewed quickly and thoroughly before they are approved. But this legislation does more than maintain the status quo; it also enacts crucial reforms that will prevent drug shortages

● This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.